

An Open-label Study to Evaluate Safety, Tolerability, and Efficacy of CB03-154 in Subjects Diagnosed With Epilepsy

NCT07238868

Status	RECRUITING
Phase	Phase 2
Sponsor	Shanghai Zhimeng Biopharma, Inc.
Enrollment	144 participants

Key Eligibility Criteria

Inclusion (4)

- \. The subject must be properly informed of the nature and risks of the study and give informed consent in writing, prior to entering the study.
- \. Subject must have successfully completed the DBP and have not terminated early from Study CB03-154-EP201, met all eligibility requirements, and had no important protocol deviations (in the opinion of the sponsor) or AEs (in the opinion of the investigator) that would preclude the subject's entry into the long-term extension study, and judged to be efficacious based on the blinded data review (in the opinion of the investigator).
- \. In the opinion of the investigator, the subject is able to understand verbal and written instructions and will adhere to all study schedules and requirements.
- \. Subject is able to keep accurate seizure diaries.

Exclusion (2)

- \- 1. Subject met any of the withdrawal criteria while in Study CB03-154-EP201. 2. Subject has any medical condition, personal circumstance, or ongoing AE (from Study CB03-154-EP201) that, in the opinion of the investigator, exposes the subject to unacceptable risk by participating in the study, or prevents adherence to the protocol.
- \. Subject is planning to enter a clinical study with a different investigational drug or planning to use any experimental device for treatment of epilepsy during the study and until 28 days after completion of this study.

Locations (1 total)

Alfred Health, Melbourne, Victoria, Australia